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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,362	05/15/2000	MARION ELKE HOFMANN	50125/008001	9849

7590 09/16/2003  
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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/16/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/445,362

Applicant(s)

HOFMANN ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-37 is/are pending in the application.
- 4a) Of the above claim(s) 24, 26, 28-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-23, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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This Office Action is in response to the election filed February 21, 2001 and the Grant of Petition mailed June 1, 2002 (Paper #20).

Applicant's election of Invention I, Claims 16-23, 25, and 27 in Paper No. Paper #7, filed February 21, 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 24, 26, and 28-37 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions.

Priority date is to June 13, 1997.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed nucleic acid is not claimed as being isolated or purified and therefore this nucleic acid reads on a product of nature.

The disclosure is objected to because of the following informalities: Taneka et al. is cited on page 3 and the sequences are disclosed therein are referred to by accession numbers. These sequences appear to be essential to the disclosure and therefore should be presented in the sequence listing.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-23, 25, and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach nucleic acids encoding functional variants (see definition at pages 5-6 of the specification) of SEQ ID NO: 4 or fragments of this nucleic acid having at least 8 nucleotides and having or encoding a polypeptide having functional activity. Therefore, the specification lacks written description of the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-23, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Taneka et al. (1996; Genomics 35: 231-235). At page 3, lines 10-18 of the specification, Applicants make of record that Taneka et al. teach an EST for the cDNA encoding the amino acid sequence depicted in SEQ ID NO: 4. Therefore, Taneka et al. teach a nucleic acid encoding SEQ ID NO: 4 and parts that are at least 8 nucleotides in length. Perusal of the alignment of SEQ ID NO: 6 with the sequence of Taneka et al. shows that SEQ ID NO: 6 is not present in the disclosed DNA encoding SEQ ID NO: 4 (**Claims 16-19**). As noted by the admission, the nucleic acid comprises SEQ ID NO: 1, NO: 2 or NO: 3 (**Claim 20**). Taneka discloses a gene; therefore, this gene comprises noncoding sequences or a polyA sequence (**Claim 21**). Taneka

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et al. isolated the genes from a library using probes (page 231, rt col, para. 1 and page 232, lt col, para 1; **Claim 25**). The DNA was cloned (page 232, rt col.); therefore the DNA was placed into a vector (**Claim 22, 23**) and expressed from a host cell (**Claim 27**) as recognized in the art of cloning.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER